K042148

DEC - 3 2004

Section 2 Summary of Safety and Effectiveness

Date: August 6, 2004

Submitter: GE Medical Systems *Information Technologies*
8200 West Tower Avenue
Milwaukee, WI 53223 USA

Contact Person: Lisa M. Baumhardt
Regulatory Affairs Specialist
GE Medical Systems *Information Technologies*
Phone: 262-293-1699
Fax: 262-293-1460

Device: Trade Name: Heart Rate Turbulence Analysis Program

Common/Usual Name: ECG Analysis Algorithm

Classification Names: 21 CFR 870.1425 Programmable Diagnostic Computer

Predicate Device: K991786 MARS Unity Workstation with Heart Rate Variability Option

Device Description: The Heart Rate Turbulence Analysis Program is a software algorithm that runs in GE Medical Systems *Information Technologies* electrocardiographic equipment.

Intended Use: The Heart Rate Turbulence Analysis Program is intended for use in a hospital, doctor's office, or clinic environment under the direct supervision of a licensed healthcare practitioner. The intended use of the Heart Rate Turbulence Analysis Program is to analyze ECG signals, provide measurements of Heart Rate Turbulence in patients undergoing cardiovascular disease testing for interpretation by qualified healthcare practitioner for the purposes of risk stratification and prediction of sudden cardiac death. The Heart Rate Turbulence Analysis Program only provides measurements, not interpretations. The Heart Rate Turbulence Analysis Program is to be used in conjunction with the patient's clinical history, symptoms, and other diagnostic tests for final clinical judgment.

Technology: The Heart Rate Turbulence Analysis Program employs the same functional technology as the predicate device for calculating variations of heart rate (RR) intervals. An enhancement was made to the reporting of the time domain measurements to include the variation in RR intervals associated with a single premature ventricular contraction (PVC).

Test Summary: The Heart Rate Turbulence Analysis Program and its host electrocardiograph comply with the voluntary standards as detailed in Section 9 of this submission. The following quality assurance measures were applied to the development of the Heart Rate Turbulence algorithm:

- Risk Analysis
- Requirements Specification Review
- Code Inspections
- Software Verification and Validation Testing

Conclusion: The results of these measurements demonstrated that the Heart Rate Turbulence Analysis Program is as safe, as effective, and performs as well as the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC - 3 2004

GE Medical Systems Information Technologies
c/o Lisa M. Baumhardt, M.T. (A.S.C.P.)
Regulatory Affairs Specialist
8200 West Tower Ave.
Milwaukee, WI 53223

Re: K042148
Trade Name: Heart Rate Turbulence Analysis Program
Regulation Number: 21 CFR 870.1425
Regulation Name: Programmable Diagnostic Computers
Regulatory Class: II (two)
Product Code: DQK
Dated: November 29, 2004
Received: November 30, 2004

Dear Ms. Baumhardt:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050. This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K042148

Device Name: Heart Rate Turbulence Algorithm

Indications For Use:

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Prescription Use__X__ OR Over-The-Counter Use____
(Per 21 CFR 801.109 Subpart D) (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Donna R. Bachmann

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K042148